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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/509,683

04/12/2005

Eigoro Yamanouchi

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01/05/2007

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ALEXANDRIA, VA 22314

EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT

PAPER NUMBER

3734

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No. 10/509,683	Applicant(s) YAMANOUCI, EIGORO	
	Examiner Lindsey Bachman	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 15 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 12 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1. ☐ Certified copies of the priority documents have been received.
 - 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to the Amendment filed on 15 September 2006.

Specification

1. The disclosure is objected to because of the following: it is the examiner's position that applicant has invoked 35 U.S.C. 112, sixth paragraph in Claim 9 by reciting "means for securing" and "means for moving". Therefore the examiner requires the applicant to clarify the record by amending the specification to "explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, or acts perform the function recited in the claim element." MPEP 2181(IV). Please note that the MPEP clearly states that "[e]ven if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means- (or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the USPTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)...." (MPEP 2181(IV)). Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

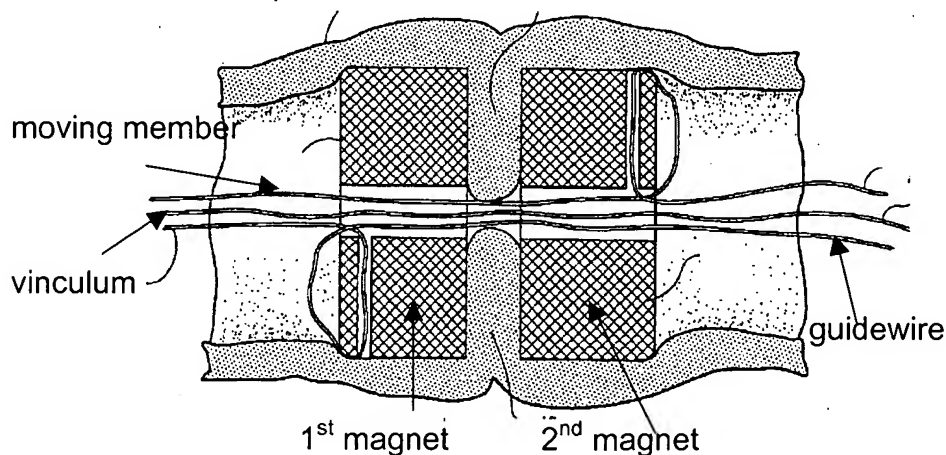
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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3. Claims 1, 5, 8, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Rudakov, et al. (SU 736966).

4. Claims 1 and 9: Rudakov'966 discloses an anastomosing device containing a flexible guidewire, a first magnet formed in a disc shape and provided with a radial through hole in order to place a guidewire, a vinculum secured through the center of the first magnet, and second magnet with a through hole and a moving member for moving the magnets. See the labeled figure below.



5. Claim 5: The device taught by Rudakov'966 has chamfered corners (see Figure).

6. Claim 8: Rudakov'966 discloses a method for performing an anastomosis that includes placing the first magnet with the vinculum at one side of an organ; introducing the second magnet over the vinculum to the other side of the magnet and moving the magnet with the moving member; and magnetically attracting the two magnets to each

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other to perform the anastomosis. (See English explanation in Cope, et al. US 5,690,656: column 1, line 60 to column 2, line 15).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. **Claim 2, 3, and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rudakov'966, as applied to Claim 1, in further view of Hayhurst (US Patent Number 5,601,557).**

10. Rudakov'966 teaches the limitations of Claims 2-4 except for a latch member, a dissolvable vinculum.

11. Claim 2 and 3: Hayhurst'557 teaches looping a suture (vinculum) (140) through a disc (130) with a latch member (center region of 132, between sutures 140) in order to have two suture members (140) available for anchoring the disc (130) (column 10, lines

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15-26). It would have been obvious to one skilled in the art at the time the invention was made to modify the device taught by Rudakov'966 with a latch member taught by Hayhurst'557 because it provides the user with two ends of the suture which can then be used for tying/anchoring the disk.

12. Claim 4: Hayhurst'557 teaches that the suture (140) can be made out of a bioabsorbable material in order to prevent long-term irritation of the surrounding tissues (column 3, lines 15-20). It would have been obvious to one skilled in the art at the time the invention was made to modify the suture (vinculum) taught by Rudakov'966 with a bioabsorbable suture taught by Hayhurst because this would reduce irritation to the surrounding tissue if the magnets were in place permanently or if they were being used temporarily in the digestive system, the magnets could pass through the digestive tract after use so that the vinculum would only be needed for placement of the device, not removal.

13. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rudakov'966, as applied to Claim 1, in further view of Bonutti (US Patent 5,527,343).

14. Rudakov'966 teaches the claimed limitations as described above except for a moving member that is a tube fitted over a guidewire.

15. Bonutti'343 teaches a method of moving a disk (10) with a guidewire going through it (50) that is moved by a pusher member (82) that is also movably mounted to the guidewire because this allows a surgeon to control movement of the disk. It would have been obvious to move the magnet with a pusher member because this allows the

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movement to be controlled and the magnet to be retained with the guidewire (column 4, line 53 to column 5, line 31).

16. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rudakov'966, as applied to Claim 1, in further view of Cole, et al. (US Patent Number 6,719,768).

17. Rudakov'966 teaches the claimed limitations as described above except for the use of a marker that indicates the magnetic pole of the material.

18. Cole'768 teaches a magnetic anastomosing device that contains a visual marker on the magnet that indicates the polarity of the magnetic field (column 16, lines 45-61). It would have been obvious to one skilled in the art at the time of the invention to modify the device taught by Rudakov'966 with a visual marker taught by Cole'768 to ensure that the orientation of the magnet relative to another device will cause the devices to be attracted to each other.

Response to Arguments

19. Applicant's arguments filed 15 September 2006 have been fully considered but are moot in view of the new ground(s) of rejection.

20. Claim 1: Applicant's arguments with respect to Claim 1 have been considered but are moot in view of the new ground(s) of rejection.

21. Claims 2, 3, and 4: In response to applicant's argument that Hayhurst'557 is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem

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with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, although the device taught by Hayhurst'557 is a bone anchor, not a magnetic anastomosing device, Hayhurst'557 is relied upon for method of solving the problem of securing the device, which matches the method claimed by Applicant.

22. Claims 5 and 7: Applicant's arguments with respect to Claim 5 and 7 have been considered but are moot in view of the new ground(s) of rejection.

23. Claim 6: Applicant's arguments with respect to Claim 6 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

25. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

26. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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A handwritten signature in black ink, appearing to read "MJ Hayes", with a stylized flourish at the end.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER